

REMARKS

This application is the U.S. National Stage of PCT/DE 00/02231.

I. Claim Changes

The originally presented claims 1 to 9 were English translations of the claims of the PCT International application. These claims were not drafted in accordance to U.S. Patent Office Rules.

New claims 10 to 20 have been added above and the original claims 1 to 9 have been canceled. New claims 10 to 20 have been drafted considering U.S. Patent Office Rules and the disclosures in the cited prior art, especially the reference of J. Allen, et al.

II. Claims directed to Non-statutory Subject Matter

Claims 7 to 9 were rejected under 35 U.S.C. 101 because they were in the form of non-statutory "use" claims.

Claims 7 to 9 have been canceled. No new "use" claims have been filed. Instead new claims 10 to 20 include method of preservation claims 10 to 15 and composition claims 16 to 20.

It is respectfully submitted that none of the new claims 10 to 20 should be rejected under 35 U.S.C. 101 for containing non-statutory subject matter.

III. Indefiniteness Rejection of Claim 6

Claim 6 was rejected for indefiniteness under 35 U.S.C. 112, second paragraph.

This claim contained the term "protic solvent". This term is a well-known term in the chemical arts. A "protic solvent" is a solvent that has hydrogen bonded to a very electronegative atom, such as oxygen, so that the hydrogen is easily released (e.g. participates in hydrogen bonding). An alcohol ROH is an example of a protic solvent. "Aprotic solvents" do not have hydrogen atoms attached to electronegative atoms and do not easily release the hydrogen atoms. An example of an aprotic solvent is acetone.

However none of the new claims use either the term "protic solvent" or "aprotic solvent". Thus the rejection of the claim wording for containing this term is moot. Claims may however be filed containing this term, if necessary, in the future, since it is a well-known and often used term, especially in the organic chemical arts.

In addition, the above claims have been checked for antecedent basis errors and for relative terms and other indefinite types of wording.

For the foregoing reasons and because of the new claim wording, it is respectfully submitted that none of the new claims 10 to 20 should be rejected under 35 U.S.C. 112, second paragraph.

IV. Claim Rejection based on J. Allan, et al.

Claims 1 to 5 were rejected as anticipated under 35 U.S.C. 103 (a) as obvious from the article by J. Allan, et al.

New claims 10 to 20 have been added and claims 1 to 5 were canceled obviating this rejection. In the following the relationship of the new claims to the subject matter of the J.Allan, et al, reference has been considered.

1. Content of J. Allan, et al

The article by J.Allan, et al, describes comparative experiments in which the antibacterial effects of adding bioactive glass 45 s 5 to media containing cultured oral bacteria were observed and measured. This bioactive glass was added to a comparatively simple nutrient broth that is low in protein but contains cultured oral bacteria. This same bioactive glass was also added to DMEM + 10 % FCS, a medium that is more like human tissue fluid, which also contains the same oral bacteria. It was found that the bioactive glass strongly (more than 95 %) inhibited the viability of the oral bacteria in the case of the simple nutrient broth, but less so in the case of the DEM + 10 % FCS. The bioactive glass contained 45 % silicon dioxide, but no silicone. It also contained Na₂O, CaO and P₂O₅, which are typical ingredients in bioactive glass.

The experiments involved several bacteria that commonly occur in the mouth, such as *Strep* bacteria. Since the researchers are from a Dental Institute clearly the interest is in applications that reduce the presence of decay causing bacteria in the mouth. For example, material used to fill cavities that includes bioactive glass has been proposed for this purpose.

2. Method Claims 10 to 15

New method claim 10 claims a different, but related, use of the bioactive glass particles. The method claimed in claim 10 is a method of preserving a cosmetic and/or pharmaceutical composition based on the antimicrobial action of bioactive glass. It is well known that pharmaceutical and/or cosmetic compositions contain compounds that act as nutrients for microorganisms such as bacteria. Thus the preservative action of the bioactive glass would expected to be less effective in these types of compositions than in the rather weak nutrient broth of J. Allan, et al, because these compounds will nourish and promote the microorganism colonies.

One skilled in the art of formulating cosmetic and/or pharmaceutical compositions would not consult the Dental Institute study of Allan, et al, regarding the antibacterial effects of bioactive glass in tissue-like fluids, especially saliva-like fluids, for hints and suggestions regarding preservative compounds for pharmaceutical and/or cosmetic compositions.

First, the J. Allan, et al, article is in a different field of art from applicants' claimed method. It is from the dental field. Thus one skilled in the art of formulating pharmaceutical compositions and/or cosmetic compositions would not be readily familiar with this field and would not have ready access to publications in this area. Not only that there is some doubt regarding whether the results of J.Allan, et al, are "reasonably pertinent" to the problem of preservation of cosmetic and/or pharmaceutical compositions because of the teaching that the antibacterial effect on the viability of the oral bacteria in the media which is high

in protein was significantly poorer than the effect in the media that is low in protein. Thus there is reasonable basis for a decision that J. Allan, et al, is non-analogous art, as far as the new method claimed in new claim 10 goes.

Second, biochemistry is still somewhat unpredictable despite the advances of recent years. Currently there is no way to accurately and quantitatively calculate the effect of adding bioactive glass to various compositions containing trace inoculations of a microorganism from a few results regarding a few particular microorganisms and two culture media.

Although obviousness does not require absolute predictability, at least some degree of predictability is required. See M.P.E.P. 2143.03 and *In re Rinehart*, 189 U.S.P.Q. 143(C.C.P.A. 1976). Here in the case of the instant method claims 10 to 20 there is no reason to expect in advance that it would be possible to preserve cosmetic and/or pharmaceutical preparations based on the antibacterial results of J. Allan, et al, obtained using the two culture simplified media containing certain oral bacteria. The cosmetic and/or pharmaceutical preparations many compounds that promote bacterial growth and are more difficult to keep free of microorganisms than the culture media in the study of J. Allan, et al, which of course has been done for a different purpose as noted above. For example, sugars and proteins are sometimes included in both types of compositions as well as vegetable oils are often included in cosmetic compositions.

Thus it is doubtful that one skilled in the art, when presented with the J.Allan, et al, would find a reasonable suggestion of the method of preservation

of pharmaceutical and/or cosmetic compositions of new claims 10 to 20. The article never mentions preserving any type of composition with bioactive glass.

Furthermore the reasoning in the Office Action is based on hindsight and the use of the disclosure of the effective preservation of pharmaceutical and/or cosmetic composition with bioactive glass in the applicants' specification. Federal Courts have consistently overturned this type of rationale for a rejection under 35 U.S.C. 103 based on hindsight and applicants' specification. For example, the Federal Circuit Court of Appeals has said:

"As in all determinations under 35 U.S.C. 103, the decision-maker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selected elements from references to fill the gaps". *In re Gorman*, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

The J. Allan, reference does not disclose preserving any composition, especially a cosmetic and/or pharmaceutical composition containing compounds that would promote microorganism growth.

For the foregoing reasons it is respectfully submitted that **none** of the new method claims 10 to 15 should be rejected under 35 U.S.C. 103 (a) for obviousness over J. Allan, et al.

3. Compound Claims 16 to 20

The new composition claim 16 claims a liquid cosmetic composition, which includes bioactive glass particles in an inconspicuous manner so that a consumer will not notice their presence. The bioactive glass is selected with a refractive index that is sufficiently close to the solvent so that the particles are

substantially invisible, except under close study. The basis for new composition claim 16 is found on page 5 of applicants' originally filed specification.

J. Allan, et al, neither discloses nor suggests the feature of selecting bioactive glass with an index of refraction that matches that of the liquid cosmetic composition.

It is well established by many U. S. Court decisions that to reject a claimed invention under 35 U.S.C. 103 there must be some hint or suggestion in the prior art of the modifications of the disclosure in a prior art reference or references used to reject the claimed invention, which are necessary to arrive at the claimed invention. For example, the Court of Appeals for the Federal Circuit has said:

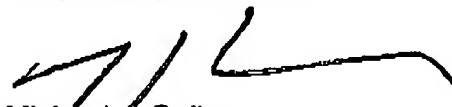
"Rather, to establish obviousness based on a combination of elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant...Even when obviousness is based on as single reference there must be a showing of a suggestion of motivation to modify the teachings of that reference.." *In re Kotzab*, 55 U.S.P.Q. 2nd 1313 (Fed. Cir. 2000). See also M.P.E.P. 2141

For the foregoing reasons it is respectfully submitted that **none** of the new claims 16 to 20 should be rejected under 35 U.S.C. 103 (a) as obvious from J. Allan, et. al.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,



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V. Information Disclosure Statements

Consideration of the Information Disclosure Statements dated June 25, 2002 and February 27, 2002 and the accompanying prior art references is gratefully acknowledged.

The Information Disclosure Statement dated January 23, 2003 and filed January 30, 2003 has been acknowledged on page 2 of the Office Action, but a copy of this Information Disclosure Statement initialed by the Examiner did not accompany the above-identified Office Action. The listing of the prior art reference accompanying this latter Information Disclosure Statement on the front cover of any patent that issues based on the above-identified application is respectfully requested as well as transmission of an initialed copy of the Information Disclosure Statement dated January 23, 2003 with the next Office Action.


Furthermore the Information Disclosure Statement filed with the initial U.S. National Stage Application papers has not been considered. This Information Disclosure Statement dated January 7, 2002 accompanied four U.S. Patent references, one WO reference in a foreign language and two Abstracts of Japanese Patent documents. Consideration of all these prior art references including the foreign language WO reference to the extent possible as required by U.S. Patent Office Rules is respectfully requested.

In addition a copy of the Information Disclosure Statement dated January 7, 2002 initialed by the Examiner should be provided with the next Office Action.

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